UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CHAMBERS OF
PAUL W. GRIMM
UNITED STATES DISTRICT JUDGE

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March 26, 2019

RE: *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*
PWG-18-883

LETTER ORDER

Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") in 2009 and, in 2016, "the Food and Drug Administration ('FDA' or 'the agency') exercised the Secretary's statutory authority to deem electronic nicotine device systems (referred to here as 'e-cigarettes'), cigars, and pipe tobacco 'tobacco products' subject to regulatory controls under the Tobacco Control Act. Compl. ¶¶ 1–2, ECF No. 1. The FDA adopted a "compliance and enforcement regime" to "accomplish the statute's public health objectives"; the regime, known as the "Deeming Rule," went into effect August 8, 2016. *Id.* ¶ 2. The FDA then issued *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* 3 ("2017 Guidance") in August 2017 regarding "the statutory duties and responsibilities of newly deemed tobacco products." *Id.* ¶ 3.

Of most significance to Plaintiffs, the 2017 Guidance "purports to exempt, on a categorical basis, manufacturers of newly deemed products from the Tobacco Control Act's premarket review regime for up to *six years* beyond the effective date of the Deeming Rule (and, in practice, indefinitely beyond that time)—notwithstanding Congress's statutory mandate that, subject to exceptions not relevant here, premarket review is 'required' before newly deemed products may be marketed or distributed to consumers." *Id.* The American Academy of Pediatrics, The Maryland Chapter – American Academy of Pediatrics, The American Cancer Society Cancer Action Network, The American Heart Association, The American Lung Association, The Campaign for Tobacco-Free Kids, The Truth Initiative, Dr. Leah Brash, MD, Dr. Cynthia Fishman, MD, Dr. Linda Goldstein, MD, Dr. Steven Hirsch, MD, and Dr. David Myles, MD filed a Complaint for Declaratory and Injunctive Relief against the FDA, Commissioner of Food and Drugs Scott Gottlieb, U.S. Department of Health and Human Services, and Secretary of Health and Human Services Alex M. Azar II. Compl. 1. They ask the Court to vacate the 2017 Guidance, claiming that it is unlawful in that it (1) "exceeds the agency's statutory authority," (2) "is an express and deliberate abdication of FDA's responsibilities under the Tobacco Control Act," (3) "was not promulgated in accordance with the APA's notice and comment requirements," despite being a substantive rule, (4) "is arbitrary and capricious and not the product of reasoned decisionmaking." *Id.* ¶¶ 4–7.

Plaintiffs, believing that "the case can be resolved without discovery or further fact-finding by any party and is therefore ripe for expeditious resolution as a matter of law," ECF No. 23, filed a Motion for Summary Judgment, ECF No. 31. Defendants then filed a Motion to

Dismiss or, in the Alternative, for Summary Judgment. ECF No. 36. They argue that Plaintiffs lack standing because the 2017 Guidance does not cause any cognizable harm to them; the Court lacks jurisdiction to review the FDA's compliance policy because the FDA has complete discretion in deciding how to enforce its rules; and the 2017 Guidance is not final agency action subject to judicial review. Defs.' Mem. 3–4. Alternatively, they contend that Plaintiffs' claims fail on the merits because the 2017 Guidance does not conflict with the Tobacco Control Act, it is a policy statement, not a rule, and therefore is except from the notice and comment requirements, and the FDA provided a rational explanation for the policy. *Id.* at 4–5.

The parties fully briefed their motions. ECF Nos. 31-2, 36-1, 39, 43. Additionally, Plaintiffs filed a Motion for Leave to File a Surreply, to "address[] two new exhibits on which FDA relies in its reply brief," exhibits that postdated Plaintiffs' most recent brief; FDA consented to the request. ECF No. 44. Plaintiffs also requested a hearing. *See id.* The Motion for Leave to File a Surreply is granted, and the Surreply, ECF No. 44-1, is accepted as filed. A hearing is not necessary at this time, however. *See* Loc. R. 105.6.

Defendants' Reply and Plaintiffs' Surreply noted that the FDA announced on September 12, 2018 that it "intends to revisit the so-called 'compliance policy embodied in the Guidance." Pls.'s Surreply 1; Defs.' Reply 1 n.1. Then, on November 15, 2018, the Commissioner "released a statement proposing a 'policy framework' for the regulation of tobacco products, including flavored e-cigarettes and cigars." Defs.' Notice, ECF No. 51; *see also Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes*, at 7, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm (Nov. 15, 2018), ECF No. 51-1. The Commissioner stated that the FDA would reconsider various "compliance polic[ies] set forth in the challenged Guidance" and "[p]ursue removal from the market of ENDS [electronic nicotine delivery systems] products that are marketed to children" and ban flavored cigars and menthol in combustible tobacco products, in light of "youth appeal and youth access to flavored tobacco products" leading to a sharp increase in use by middle and high school age children. Defs' Notice 1–2. Plaintiffs responded that "[t]he Commissioner's statement . . . neither undermines Plaintiffs' claims in this case nor eliminates the need for prompt relief from FDA's illegal action." ECF No. 53.

Most recently, "on March 13, 2019, the FDA published draft guidance that, if finalized, would modify the August 2017 Guidance challenged in this case." Defs.' Second Notice, ECF No. 59; *see also* FDA, Draft Guidance for Industry, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* (March 2019), *available at* https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf, ECF No. 59-1; *Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new policies aimed at preventing youth access to, and appeal of, flavored tobacco products, including e-cigarettes and cigars*, at 2 (Mar. 13, 2019), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633291.htm , ECF No. 59-2. If finalized, the Draft Guidance would, *inter alia*, "modify the policy of deferred enforcement" for "most flavored e-cigarette products" and "prioritize enforcement of the premarket review requirement" against most flavored e-cigarette products and all e-cigarette products "targeted to minors or likely to promote use . . . by minors." Defs.' Second Notice 1–2. Defendants noted that "[t]he FDA is accepting public comments on the draft guidance for a 30-day period that closes on April 15, 2019," and, "[i]f finalized, the agency has proposed that the

revisions to its compliance policy take effect 30 days after the publication of a final guidance document." *Id.* at 3. In response, Plaintiffs contend that "FDA's latest announcement is merely a *draft* guidance with no legal effect, leaving the challenged 2017 Guidance in full force," and, [e]ven if finalized tomorrow, the draft policy would remain unlawful and Plaintiffs' claims justiciable." ECF No. 61.

Plaintiffs cannot challenge the Draft Guidance before it is finalized because, as Plaintiffs note, it is the 2017 Guidance, not the Draft Guidance, that is in effect. Further, given that the Draft Guidance, if finalized, will supplant the 2017 Guidance—the focus of Plaintiffs' claims in this lawsuit—and perhaps necessitate an amendment to Plaintiffs' Complaint, it is premature and would be neither efficient nor a wise allocation of resources to consider Plaintiffs' Motion for Summary Judgment at this time, when the very guidance that Plaintiffs' challenge is subject to possible imminent revision. *See* Fed. R. Civ. P. 1 (stating that the Federal Rules of Civil Procedure "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding."). Therefore, it is denied without prejudice to renewal following the FDA's finalization, or rejection of the Draft Guidance. And, because Defendants' justiciability arguments cannot fairly be considered in a vacuum, when the object of Plaintiffs' grievances is in flux, I will deny Defendants' Motion for Summary Judgment without prejudice at this time as well.

Accordingly, ECF Nos. 31 and 36 are denied without prejudice, and ECF No. 44 is granted. I caution, however, that the purpose of this Order is to suspend a ruling on the issues raised by the parties until such time that any decision regarding the revision of the 2017 Guidance has been made, with the expectation that this will be done in the very near future. Should the process become more prolonged, then I will revisit this Order, and, if I determine that the Defendants' actions are for the purpose of delay, rather than to substantively re-evaluate the current Guidance, then I will withdraw this Order and issue a ruling as promptly as my schedule will permit. To facilitate this review, the parties shall submit a status report every month, beginning on May 15, 2019, informing me of the status of the proposed revision of the Guidance.

Although informal, this is an Order of the Court and shall be docketed as such.

Sincerely,

/S/
Paul W. Grimm
United States District Judge

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